

MAZIE SLATER KATZ & FREEMAN, LLC

103 Eisenhower Parkway, Suite 207, Roseland, NJ 07068

Phone: (973) 228-9898 - Fax: (973) 228-0303

www.mazieslater.com

David A. Mazie*
Adam M. Slater*
Eric D. Katz*
David M. Freeman
Beth G. Baldinger
Matthew R. Mendelsohn
David M. Estes

*Certified by the Supreme Court of
New Jersey as a Civil Trial Attorney

Member of N.J. & N.Y. Bars

Karen G. Kelsen
Cheryll A. Calderon
Adam M. Epstein
Cory J. Rothbort*
Michael R. Griffith
Christopher J. Geddis
Alexander Q. Reynoso
Samuel G. Wildman
Julia S. Slater

February 23, 2021

VIA ECF

Honorable Robert Kugler, U.S.D.J.
U.S. District Court - District of New Jersey
Mitchell S. Cohen Building & US
Courthouse
1 John F. Gerry Plaza, Courtroom 4D
4th and Cooper Streets
Camden, New Jersey 08101

Honorable Thomas I. Vanaskie (Ret.)
Special Master
Stevens & Lee
1500 Market St., East Tower, Suite 1800
Philadelphia, Pennsylvania 19103-7360

Re: ***In re Valsartan, Losartan, and Irbesartan Liability Litigation,***
Case No. 1:19-md-02875-RBK (D.N.J.)

Dear Judge Kugler and Judge Vanaskie:

Please accept this letter on behalf of the Plaintiffs in advance of the February 24, 2021 case management conference.

1. Plaintiff Deposition Issues

During the exchange of agenda items that occurred yesterday, Defendants first notified Plaintiffs that they intended to raise the issue of the Class Plaintiffs' "technological readiness for depositions" with the Court. Given the fact Defendants had not even requested a formal meet-and-confer to discuss the supposed issue of "technological readiness," Plaintiffs do not view this topic as ripe for Court intervention at this time.

Honorable Robert Kugler, U.S.D.J.
Honorable Thomas I. Vanaskie (Ret.)
February 23, 2021
Page 2

However, to the extent there is any suggestion by Defendants to the contrary, Plaintiffs have sought to ensure that the depositions of the Class Representatives could proceed smoothly. These efforts have included Plaintiffs' counsel traveling in person to allow for the depositions of physically handicapped class representatives without video conferencing capabilities to proceed. Plaintiffs also note that the court reporting service chosen by Plaintiffs (which is different from the one chosen by Defendants) has made an effort to contact counsel and the witnesses in advance, where possible, and conduct testing of the defense witness's internet capabilities and connectivity in order to ascertain any issues that may occur and address them ahead of time. This has resulted in minimal technical issues. Despite this effort, however, Defendants' witnesses have still encountered technological problems of their own during the depositions and when they occur, Plaintiffs' counsel has waited for them to be resolved and proceeded with the deposition understanding that Zoom depositions will not always go as smoothly as we might like. The issue of "technological preparedness" goes both ways. Indeed, just yesterday Counsel for Teva informed Plaintiffs that Teva's regulatory affairs officer has issues utilizing Zoom and/or the internet, and would require hard-copy documents due to these technological issues. Plaintiffs agreed in order to facilitate the process for all involved.

Nevertheless, Plaintiffs are prepared to meet-and-confer with Defendants to address whatever issues they may have.

2. Dismissal of Peripheral Defendants

The Court previously entered a stipulated order relating to Peripheral Defendants as to Valsartan Defendants. With the Losartan and Irbesartan Master Complaints now on file, the

Honorable Robert Kugler, U.S.D.J.
Honorable Thomas I. Vanaskie (Ret.)
February 23, 2021
Page 3

Parties have negotiated a similar order. The Parties are working though one final clause in the agreement and expect to have this submitted to the Court shortly.

3. Bellwether Plaintiffs with Dismissed Claims

The Parties have held productive meet and confer sessions to discuss issues associated with the entry of a Bellwether order. With respect to this order, the only remaining dispute between the parties concerns dismissal procedures for Bellwether cases. Defendants suggest that Bellwether cases may only be dismissed by court order on terms that the Court considers proper. Plaintiffs believe this language is unnecessary. In the Benicar litigation, cases were selected for the bellwether pool by random selection. There, the Court allowed bellwether cases to be dismissed and to be replaced again by random selection. Here, the parties have each selected a set of cases for work-up. Thus, Plaintiffs propose that if a Bellwether case is dismissed, the party who selected that case for the pool may pick a replacement. This procedure would allow Defendants to re-select a case for the pool if a case in their original selection is dismissed, thereby alleviating the concern that dismissal of a case in the Defendants' set would upset the balance of the pool.

4. Plaintiff Fact Sheets/Show Cause Requests

The Parties had a global meet and confer on Plaintiff Fact Sheets last week and have narrowed the list of Plaintiffs with outstanding deficiencies. Plaintiffs are prepared to address any remaining deficiencies relating to any Plaintiffs listed in Defendants' agenda letter.

5. Hetero Discovery Status

During the February 17, 2021 status conference, it was agreed that the Parties would provide an update at the February 24, 2021 discovery conference with regard to the extensive deficiencies in Hetero's disclosures and productions. Since that time, the Parties have

Honorable Robert Kugler, U.S.D.J.
Honorable Thomas I. Vanaskie (Ret.)
February 23, 2021
Page 4

communicated multiple times, including meet and confer conference calls. While Plaintiffs are encouraged that Hetero has acknowledged the extent and significance of the deficiencies, it remains to be seen whether Hetero will remedy the situation as emergently as is required, in light of the narrow window remaining for depositions and the significant extent of the problems.

During the most recent conference call on February 22, 2021, Hetero represented that they were in active discussions with their client and their vendor in an effort to address the various issues, and advised of the following: (1) the full cast of characters for the privilege log will be produced this week, (2) the large number of outstanding standard operative procedures and similar/related documents (i.e. all draft and final versions of the Quality Systems Manual) will be produced this week (note: this outstanding production could impact the deposition scheduled March 3-4 with regard to application of cGMP's/SOP's), and (3) requested hit count reports on the custodians will be provided this week.

Hetero also catalogued its ongoing efforts to remedy multiple other significant issues, including but not limited to: (1) fixing the metadata inaccuracies and deficiencies, including for example the inaccurate entries in the custodian field, and working with Plaintiffs to identify the proper form of export file to accomplish this – this is an area that will likely require extensive repair, (2) compiling and reviewing documents of custodians for whom no productions were made, (3) figuring out whether hard copy documents were collected and produced, and if so how identified; and in any case either remedying the lack or inaccuracies in metadata or collecting and producing these documents in a format compliant with the ESI protocol, (4) identifying for Plaintiffs all applications/software/databases/sharepoints, etc. that contained documents and information responsive to Plaintiffs' requests for production, and confirming to what extent

Honorable Robert Kugler, U.S.D.J.
Honorable Thomas I. Vanaskie (Ret.)
February 23, 2021
Page 5

productions were or were not made from these important data sources, and remedying any shortcomings – in this connection it appears clear to Plaintiffs that significant responsive data and documents was not collected or produced, including for example relevant test results, (5) confirmation as to the extent of documents and information that may have been maintained by Hetero's wholly owned subsidiary and sole US distributor Camber Pharmaceuticals, but not produced, (6) identification and production of numerous documents identified by Plaintiffs as missing from the production – based on cross-referencing in other documents – or incompletely produced, for example missing pages. Additional work is apparently being focused on the privilege log descriptions, the production indexes, and Plaintiffs' challenges to confidentiality designations.

Plaintiffs are willing to continue to work with Hetero, in light of Hetero's representations and stated commitment to quickly fix these extensive problems, as long as this does not end up prejudicing Plaintiffs. Due to the extent of these material issues, and the small amount of available time, Plaintiffs reserve the right to seek concrete relief, including but not limited to firm, expeditious deadlines, or potentially more significant discovery sanctions, in the event that this process slows or fails to yield documents and information that remedies these shortcomings on the condensed timeline available to the parties. This may also include the need to modify the deposition schedule if necessary due to the pace of production, for example the upcoming March 3-4 deposition.

6. Camber Deposition Status

Camber is Hetero's wholly owned subsidiary, and sole distributor in the United States. Camber has produced documents, and Plaintiffs are working to confirm the adequacy of those

Honorable Robert Kugler, U.S.D.J.
Honorable Thomas I. Vanaskie (Ret.)
February 23, 2021
Page 6

productions, including a “P Drive” that is believed to contain relevant documents. In the past several days, the Plaintiffs and Camber/Hetero confirmed the 30(b)(6) topics to be addressed by Camber witnesses, and Camber identified its witness and proposed dates this afternoon, so that can be finalized – hopefully in time to be confirmed at the conference. As the Court is aware, the depositions for all manufacturers have been scheduled, and this related deposition(s) is the only remaining open item.

7. Privilege Log Deficiency Status

The Parties have fully briefed this issue.

8. ZHP Protective Order Status

ZHP filed its reply brief on February 10, 2021. (ECF 858). During the February 17, 2021 status conference, the Court indicated that it may decide the motion on the papers. Accordingly, Plaintiffs clarify two factual inaccuracies in ZHP’s reply brief. First, ZHP stated that Yuelin Hu “is not listed as giving the final approval for the Change Request Form—the person listed is Cunxiao (Jenson) Ye, who has been appointed by ZHP to be a ‘Qualified Person.’” (Def.’s Reply Br. 6). This is misleading at best. [REDACTED]

[illegible]

Honorable Robert Kugler, U.S.D.J.
Honorable Thomas I. Vanaskie (Ret.)
February 23, 2021
Page 7

[REDACTED]

[REDACTED] These exhibits as well as the dozens submitted with Plaintiffs' opposition brief clearly establish that Ms. Hu is ZHP's managing agent.

9. Aurobindo Discovery Status

a. Document Hit Counts

Since the discovery conference last week, Plaintiffs and Defendants have continued to meet and confer. Aurobindo since agreed to provide hit counts for each custodian by the end of this week and consequently did not file a brief with the Court on that issue earlier this week.

b. Custodians from Aurobindo Pharma, Ltd.

The Parties have also been meeting and conferring regarding custodians from Aurobindo Pharma, Ltd. At this time, the Parties have reached agreement as to the following individuals:

1. Mr. Mallikarjun (Unit 7 Operations Head)
2. Mr. Pravatkumar Tripathy (Unit 7 Quality In-charge)

¹ Plaintiffs note that their Opposition essentially pointed this out when it stated that [REDACTED]

(Pls.' Br. 7).

Honorable Robert Kugler, U.S.D.J.
Honorable Thomas I. Vanaskie (Ret.)
February 23, 2021
Page 8

3. Mr. Sarath kumar Kamavarapu (API Unit XI Quality In-charge)
4. Mr. M V Rama Krishna (API Unit XI Operations Head)
5. Mr. Hanumanthu Penchalaiah (Global Pharmacovigilance Head)
6. Mahesh B. Shinde (Quality Head - Unit 7)
7. Dr. Srinivas K Rama (Quality Head - Unit 11)

Aurobindo is in the process of verifying that these custodians cover the whole Relevant Time Period for discovery. To the extent they do not, Aurobindo has agreed to provide the custodial files of any other individuals who held any of the above job titles during the Relevant Time Period.

Plaintiffs also proposed the following individuals, each of whom is mentioned in Aurobindo's Risk Assessment (APL-MDL 2875-0023509) of its NDMA contamination in its VCDs:

1. MV Subba Raju (Manufacturing Department)
2. T Rajasekhar Reddy (Manufacturing Department)
3. P. Sateesh Kumar (Manufacturing, Science, and Technology)
4. GV Srinivasa Sudhakar Varma (Engineering & Utility)
5. N Somasundaram (Quality Control)
6. A Srinivasa Reddy (Warehouse)
7. R Srinivasa Rao (Quality Assurance)
8. A Srikanth (Quality Assurance)

Each of these individuals was important enough that she or he was placed in charge of investigating Aurobindo's contamination, which formed the basis for this case. Aurobindo claims that the custodians it agreed to cover the issues on which these additional custodians would have

Honorable Robert Kugler, U.S.D.J.
Honorable Thomas I. Vanaskie (Ret.)
February 23, 2021
Page 9

knowledge, but this cannot be the case. For example, no custodian agreed to by the parties has a job title that overlaps with any of the custodians here. (This raises questions about the adequacy of the 30 b 6 representatives named by Aurobindo but Plaintiffs are aware that they cannot press this issue unless and until a 30 b 6 representative turns out to be inadequate). For this reason, the Plaintiffs ask that the Court order Aurobindo to produce these custodial files.

Plaintiffs also asked that Aurobindo provide the names of the individuals who, during the Relevant Time Period, were charged with the following:

1. Contracting with Lantech (the supplier of NDMA contaminated solvents to Aurobindo);
2. Conducting due diligence on Lantech in terms of quality and cGMP compliance;
3. Providing Lantech with specifications for the use, recovery, recycling, and cleaning of the solvents used in the manufacture of Aurobindo's VCDs; and
4. Investigating any cGMP, contamination, or NDMA issues with Lantech.

To date, Aurobindo has not provided the names of these individuals, even though these are among the most important and obvious custodians. Plaintiffs request that the Court order Aurobindo to provide Plaintiffs with the names of all individuals responsible for the items above by the end of the week and that Aurobindo further agree to produce those individuals' custodial files.

c. Production Dates for Documents from Aurobindo Pharma, Ltd.

The first Aurobindo deposition is scheduled for March 12, which is less than three weeks away. Other depositions are scheduled for March 19 and 25, with the rest to follow. Plaintiffs have asked Aurobindo for a firm commitment on production dates for documents and has yet to

Honorable Robert Kugler, U.S.D.J.
Honorable Thomas I. Vanaskie (Ret.)
February 23, 2021
Page 10

receive one. Plaintiffs therefore request that the Court order the following phased production, on a rolling basis:

- No later than March 5, 2021: The production of the custodial files of Mr. Hanumanthu Penchalaiah, and all Lantech related custodians be completed; and
- No later than March 12: All remaining productions of custodial files must be completed.

The alternative is not feasible. If Aurobindo is permitted to roll out documents slowly, this will disrupt the deposition schedule, and place Plaintiffs' deposition team under enormous pressure that would be entirely unfair. The schedule outlined above already places tremendous pressure on Plaintiffs to review these documents within days of the deposition dates, and any further delay should not be permitted.

10. Status of Service on Losartan/Irbesartan Foreign Defendants

Shortly after filing the Master Pleadings for Irbesartan and Losartan, Plaintiffs send waivers of service to all known counsel for each Defendant and separately initiated service via the Hague Convention as to foreign defendants. Plaintiffs are attaching a spreadsheet detailing the profess of serving each Defendant and note that there are still a number of defendants who have not waived service. (Ex. Q hereto).

Just as in Valsartan, Plaintiffs request that for any foreign entity who is not also named as a defendant in the valsartan master pleadings, the Court require Plaintiffs to serve that Defendant only once via the Hague Convention and that from that time onward, Defendants must accept service of all complaints via the Court's Case Management Orders in this case.

Honorable Robert Kugler, U.S.D.J.
Honorable Thomas I. Vanaskie (Ret.)
February 23, 2021
Page 11

For any foreign defendant who was named in the valsartan pleadings and who is also named in the losartan and/or irbesartan master pleadings, Plaintiffs request that the Court require those defendants to waive formal service of process, as they have certainly received adequate notice of the claims and have been advised for months prior to the filing of the master pleadings that they would be named defendants in these actions.

Respectfully,



ADAM M. SLATER